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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,609	02/21/2006	Helen Hawai-an Lee	37945-0074	8777

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HELLER EHRMAN LLP
4350 La Jolla Village Drive, 7th Floor
San Diego, CA 92122

EXAMINER

TREYGER, ILYA Y

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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10/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,609	Applicant(s) LEE ET AL.	
	Examiner ILYA Y. TREYGER	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/25/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-33 canceled.
2. Claims 34-56 are new.
3. Claims 34-56 are examined on the merits.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

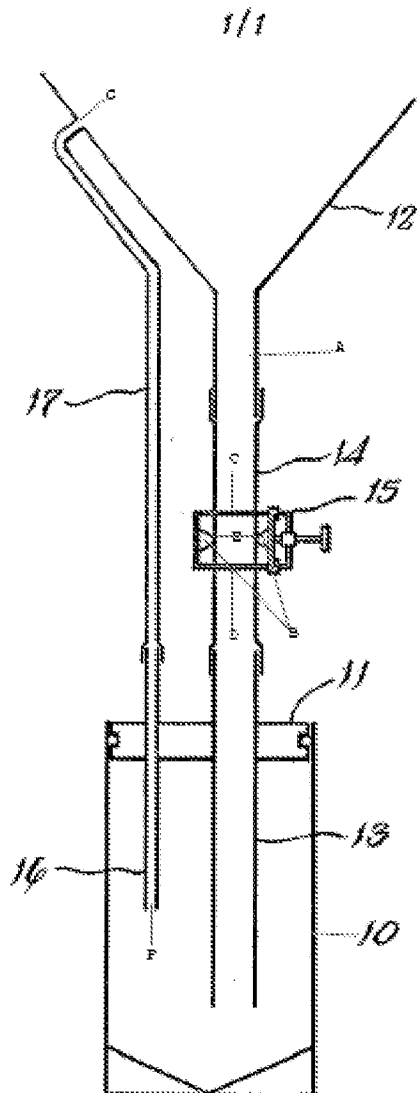
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 34-44, 46, 48, 49, 51-53, 55, and 56 under 35 U.S.C. 102(b) as being anticipated by KAVANAGH et al. (WO 861 03394). In Re claim 34, KAVANAGH discloses device, which is a sampler, for separating a predetermined initial volume of a liquid comprising an upper portion A (Fig.), a valve portion 15 (Fig.), and a container 10 (Fig.) which is a sample chamber, wherein the upper portion comprises a sample inlet and the valve portion comprises:

a valve inlet C (Fig.) coupled to the sampler inlet;

a valve outlet D (Fig.) opening into the sample chamber, wherein the valve outlet is positioned substantially below the valve inlet; a shut-off chamber separating the valve inlet from the valve outlet, which is defined by dimensions of the working parts E of the valve elements B; and

a capillary tube 16 (Fig.) which is a shut-off valve wherein the internal space of the capillary tube 16 is a shut-off chamber overflow (See Abstract, lines1-13; Fig.).



6. In Re claims 35 and 36, KAVANAGH discloses the sampler wherein the valve outlet D is aligned with the valve inlet C (claim 36), and wherein the valve outlet has larger transverse dimensions than the valve inlet (claim 35), since the deformation of the tube 14 forms conical shape while valve elements B are moving (Fig.).

7. In Re claims 37 and 38, KAVANAGH discloses the sampler comprising a tube 16, 17, which is a vent tube extending between a vent inlet F (Fig.) and a vent outlet C (Fig.), wherein the vent inlet is positioned within the sample chamber 10 (Fig.) and the vent outlet is positioned

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at a level above the valve outlet (claim 37), and wherein the level of the vent inlet within the sample chamber determines the level of liquid to be collected within the sample chamber (claim 38), since the tube 16 is a capillary tube (See Abstract, line 5).

8. In Re claim 39, KAVANAGH discloses the sampler wherein the vent outlet G (Fig.) opens into a funnel 12 (Abstract, lines 5, 6; Fig.) which extends upward from the valve portion 15 (Fig.).

9. In Re claim 40, KAVANAGH discloses the sampler wherein after the first portion of the liquid flow is collected in the sample chamber 10, further liquid flow entering the capillary tube 16 during use drains through the tubes 16, 17 (See Abstract, lines 7-13; Fig.).

10. In Re claims 42-44, KAVANAGH discloses the sampler wherein the sampler inlet comprises an upper portion A (Fig.) which is a first-catch reservoir opening into the valve inlet C (claim 41), comprising a space positioned in the funnel 12 (claim 44) at an upper end of the first-catch reservoir opening into the valve inlet (claim 42) (See Fig.).

11. In Re claim 46, KAVANAGH discloses the sampler wherein the sample chamber 10 (Fig.) is removable (See Page 5, lines 7-11).

12. In Re claims 48 and 49, In Re claim 2, Applicant sets forth the manner in which the claimed apparatus operates. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, KAVANAGH discloses the sampler fully capable of sampling a first-void urine sample when a flow of urine is introduced into the upper portion (claim 48), and of collecting the first-void urine sample in the sample chamber and later-voided urine is diverted away from the

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sample chamber (See Abstract, lines 1-13; Page 5, lines 7-11; Fig.). As such, the instantly claimed apparatus is unpatentable over the cited prior art.

13. In Re claims 51 and 55, KAVANAGH discloses a method for sampling a liquid flow using a device, which is a sampler, for separating a predetermined initial volume of a liquid, wherein:

the liquid sample is delivered by the funnel 2 and inlet tube 13 into container 10 until the level reaches the bottom of capillary tube 16, whereupon substantially no further liquid can enter the container 10. The shut-off valve 15 is then closed to prevent any further liquid from passing down the inlet tube 13. Thus, a known initial volume determined by the height of capillary tube 16 is collected (See Abstract, lines 7-13; Fig.).

14. In Re claim 52, KAVANAGH discloses the method wherein the predetermined level is at an exit of the valve outlet (Fig.).

15. In Re claims 53 and 56, KAVANAGH discloses the method wherein the portion of the liquid flow collected in the sample chamber reaches the predetermined level such that further liquid flow is fully capable of being drained through the capillary tube (valve overflow) (See Abstract, lines 7-13).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over KAVANAGH et al. (WO 861 03394) in view of THOMAS (US 3,010,805).

KAVANAGH discloses the invention discussed above, as applied to claim 44, but does not expressly disclose the sampler, wherein the funnel of sampler comprises a baffle for reducing turbulence within the device.

THOMAS discloses a funnel comprising a baffle 105 (Fig. 2) for reducing turbulence within the device (Col. 2, lines 65-68).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the funnel of KAVANAGH with the baffle, as

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taught by THOMAS in order to reduce turbulence within the device (THOMAS, Col. 1, lines 61-67).

20. Claims 47, 50, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over KAVANAGH et al. (WO 861 03394) in view of McDonald (US 3,982,898).

KAVANAGH discloses the claimed invention discussed above, as applied to claims 34 and 48, but does not expressly disclose the sampler comprising a second collection means for separation different portions liquid flow.

McDonald discloses the urine collection device comprising a plurality of chambers (collection means) for separating different portions of urine samples (See Abstract, 1-19).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the sampler of KAVANAGH with the additional collection means, as taught by McDonald in order to separate compartments for provision of multiple tests (McDonald, Col. 1, lines 25-27).

21. In Re claim 54, KAVANAGH . discloses the claimed invention discussed above, as applied to claim 51, but does not expressly disclose the method for collecting a second portion of the liquid flow, wherein the second liquid flow portion is other than a first portion of the liquid flow.

McDonald discloses the method of urine collection by the device comprising a plurality of chambers (collection means) for separating different portions of urine samples (See Abstract, 1-19).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the sampler of KAVANAGH with the additional

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collection means, as taught by McDonald in order to separate compartments for provision of multiple tests (McDonald, Col. 1, lines 25-27).

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 3,831,446 disclose the APPARATUS FOR MEMURING AVERAGE FLOW RATE.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Ilya Treyger/

Examiner

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/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761